III. STATUS OF THE CLAIMS

Claims 1-2 and 4-13 are pending in this application. Claim 3 stands cancelled.

IV. RESPONSE TO THE EXAMINER'S ANSWER

The examiner's obviousness position can be summarized as follows:

- McCormick and Copeland disclose automated methods for applying reagents to a sample located on a slide and mixing the reagents with an air stream. *See* Final Rejection at p. 3;

- McManus teaches that unstable staining solutions are made from stable ingredients;

- The examiner admits that the prior art does not explicitly teach or suggest the sequential addition of [stable components of an unstable staining solution]" to a biological sample. *See* Final Rejection at p. 4;

- The examiner nonetheless concludes that "it would be obvious to those in the art to use the automated devices of McCormick and Copeland wherein the staining reagent being mixed is the result of two or more different components to [form] and unstable dye, where in the components had been sequentially added to the material" because:

    - Copeland "does not preclude" those in the art from understanding that the stains may be mixed using the disclosed mixing process *Id.*, at p.4;
    - Stokes discloses applying more than one reagent of a combination of reagents in an individual step implying that multiple reagents may be involved in a single staining step *Id.* at p. 5; and
    - Because one of ordinary skill in the art would understand that the term reagent as used in the prior art should be given its broad dictionary definition to include individual staining ingredients as well as a final stain product. *Id.*

The Examiner's Answer crystallizes the disputed issues that must be decided by the Board. The central issues in dispute in this appeal include:

1. Whether or not the examiner is correct in the assertion that one of ordinary skill in the art would understand Copeland to teach what it "does not preclude";
2. Whether a single sentence of the Stokes et al. reference case teaches that multiple reagents, including ingredients of a stable staining solution, may be applied in a single staining step; and

3. Whether one of ordinary skill in the art would interpret the term "reagent" as used in context of the cited prior art references or as it is defined in a dictionary.

A. The Board Must Allow All Pending Claims Because The Examiner's Obviousness Rejection Picks and Chooses From The Prior Art Teachings And Is Not Based Upon What The Cited References Teach As A Whole

A *prima facie* case of obviousness cannot be constructed without showing that all of the features of the claimed invention are found in the prior art. *See e.g., In re Rouffet,* 199 Fed.3d 1350, 1359 (Fed. Cir. 1998). In rendering an obviousness rejection, the examiner may not pick and choose from reference teachings. *See, e.g., Bausch & Lomb, Inc. v. Barnes-Hynd Hydrocurve, Inc.*, 796 F.2d 443 (Fed.Cir. 1986). Here, the examiner' obviousness rejection relies upon the Copeland reference - for what it does not teach - and it relies upon a single sentence of the Stokes et al. reference taken out of context. When properly considered for what Copeland and Stokes et al. teach as a whole, the Board will have no choice but to conclude that there is no *prima facie* case of obviousness because the features of the claimed invention the examiner attributes to Copeland and Stokes et al. are not found in the references.

1. The Examiner's Rejection Improperly Relies Upon Copeland For What It Does Not Prohibit Instead Of For What It Teaches

In the Final Rejection and in the examiner's Answer, the examiner conceded that the cited references "do not explicitly teach or suggest the sequential addition of [stable components of an unstable staining solution]" *See* 11/18/2003 Final Rejection at p. 4. The examiner further admitted that Copeland teaches that only one staining reagent is applied between washes. However, the examiner takes the position that the claimed element of applying multiple ingredients of an unstable solution is disclosed in Copeland because Copeland "does not preclude those in the art from understanding that the stains may be mixed, using the mixing process disclosed by the reference, from sequentially added components that together form the reagent." (Examiner's Answer at pp. 7-8).

It is improper for the examiner to attribute a teaching to the Copeland reference that is not expressly found in their reference. *See In Re Evanega,* 829 F.2d 1110, 1112 (Fed. Cir.

1987). In *Evanega*, the Federal Circuit overturned an obviousness rejection where a claimed invention was directed to a composition in a non-isolated solution. The prior art reference - included five examples, four of which expressly required isolation of the solution component and fifth that was silent about an isolation step. *Id.* The Federal Circuit concluded that when read together in context, the fifth example could not be interpreted as an affirmative statement of no isolation. *Id.*

In the Final Rejection in this case, the examiner relied upon Copeland for something the reference "does not preclude". The examiner admits that Copeland as a whole only expressly those of ordinary skill in the art that one staining reagent is applied between washes. The examiner's position that Copeland may be relied upon for something that does not teach is contrary to law and must be rejected by the Board. The Board must consider Copeland as a whole and conclude that Copeland does not disclose as the examiner admits, the claimed feature of sequentially adding components to a slide that together form unstable staining as required by all of the pending claims.

2. The Examiner's Obviousness Rejection Relies Upon An Interpretation Of A Single Sentence Of The Stokes et al. Reference That Is Inconsistent With The Teachings Of Stokes et al. As A Whole

The examiner relies upon Stokes, in the alternative, for teaching that multiple reagents may be added to a sample to be stained in a single step. In support of this position, the examiner relies upon a single sentence of Stokes for disclosing this element. However, the examiner failed to consider the single sentence of Stokes in the context of the reference as a whole as the law requires. When considered in the context of the reference as a whole, the single sentence does not disclose applying components that together form a reagent in a single step.

The teachings of prior art references must be considered in their entirety when using the references in the obviousness rejection. In *Bausch & Lomb, Inc. v. Barnes-Hynd Hydrocurve, Inc.*, the Federal Circuit overruled an obviousness rejection where a single line in a prior art reference was taken out of context. 796 F.2d 443, 448 (Fed.Cir. 1986). In *Bausch & Lomb*, the Federal Circuit concluded that considering only a single line of a prior art reference which was taken out of context was an improper hindsight analysis. *Id.*

The examiner's obviousness rejection relies upon a single sentence of Stokes et al. and taken out of context of the remainder of the reference. A proper analysis of Stokes requires that the single sentence be interpreted in view of the reference as a whole. The applicants as demonstrated below, the sentence relied upon by the examiner, when considered in the context of the entire reference, does not support the examiner's obviousness rejection. As a result, the board cannot sustain the examiner's obviousness rejection.

The Examiner cited column 10, lines 34-38 of Stokes et al. for disclosing the concept that "multiple reagents may be applied as part of the single staining step". (See page 5 of the November 18, 2003 Official Action). The cited excerpt states:

> "Where the claims are directed to a step in the staining process, it is understood that the step may comprise a single step where a combination of reagents are applied or sequential steps where more than one reagent or combinations of reagents is applied."

A complete reading of Stokes et al. shows that the examiner interpreted this excerpt in a vacuum and did not consider the sentence in the context of the reference as a whole.

Stokes et al. is directed to a method whereby biological samples on slides undergoing staining have reagents sequentially sprayed onto the slides. Figures 1 and 2 and Examples 1 and II and the specification of Stokes et al. disclose methods for applying a sequence of solutions, to biological samples located on slides. All of the solutions are premixed solutions. In no instance is there a disclosure or suggestion that ingredients of a staining solution are applied sequentially to a biological sample to form a staining solution on the biological sample.

Upon reading Stokes et al. in its entirety, it is clear that what is taught by the excerpt relied upon by the examiner is that, for purposes of interpreting the claims, the multiple steps of, for example, the staining procedure of Example 1, may together be referred to as a "step" as that word is used in the claims. The excerpt cited by the examiner cannot in the context of the Stokes et al. patent as a whole be construed to mean – as the examiner suggests - that multiple reagents "ingredients" may be applied as part of a single staining step to form a staining solution because there is absolutely no disclosure in Stokes et al. that would support this interpretation of the cited sentence. The applicants respectfully ask the Board to consider the single sentence of Stokes et al. relied upon by the examiner in the context of the entire reference and hold that the excerpt does

not support the examiner's obviousness rejection.

B. The Reagents Used In The Prior Art Devices Are Not Ingredients That Are Admixed To Form Useful Solutions And The Examiner's Reliance On The Reagent Dictionary Definition Is Misplaced

The examiner makes as a similar mistake in his interpretation of the term "reagents". The examiner looks beyond the prior art references and their use of the term "reagent" and give the term a broad dictionary definition. When considered in the context of the prior art references, the term "reagent" is not used as the examiner interprets the term.

In Copeland and Stokes, reagents are solutions that are immediately useful when applied to a biological sample. Such "reagents" include premixed staining solutions. In contrast, the claimed invention requires that ingredients of reagents be applied separately to a biological sample where they are admixed to form a useful reagent and in particular, an unstable staining solution.

The examiner's citation of an excerpt from a disclosure on a "periodic acid Schiff reaction" does not alter this interpretation because the Examiner sought out this definition, in hindsight, in order to define the term reagent in a manner that is contrary to its teaching use in the cited references. When considered as a whole, one of ordinary skill in the art would understand that the reagents of McCormick, Copeland and Stokes disclose the pre-mixed unstable staining solutions of McManus and not individual staining solution ingredients.

The examiner's interpretation of the term "reagent" to include ingredients of a useful solution is not supported by the Stokes, Copeland or McCormick references when those references are considered in their entirety. The applicants ask the Board to adopt the applicants interpretation of the term "reagent" as it is used in the cited prior art.

C. The Examiner's Obviousness Rejection Is Based Upon Hindsight

The applicants' hindsight position parallels their position regarding the non-obviousness of the claimed invention. It is apparent that the examiner's obviousness rejection is based upon a hindsight analysis of the prior art with the applicants' invention in mind. If this were not the case, then the examiner would not have relied upon Copeland for something it does not teach nor would the examiner have relied upon a single sentence of the Stokes et al. reference taken out of context

in rendering the obviousness' rejection in this case.

In assessing the differences between the prior art and a claimed invention under Section 103, the invention must be considered as a whole. *Ruiz v. A.B. Chance Co.,* 357 Fd.3 1270, 1275 (Fed. Cir. 2004). Without the important requirement of considering the current invention as a whole, an obviousness assessment might be made by breaking the invention into its component parts and then finding a prior reference corresponding to each component. *Id.* The "as a whole" assessment requires a showing that one of ordinary skill the art at the time of the invention, confronted by the same problem and with no knowledge of the claimed invention would have selected the various elements from the prior art and combine them in the claimed manner. *Id.* In this case, the examiner combines the prior art in hindsight in a manner that is contrary to the teachings of the references as a whole and in a manner that is contrary to how a person of ordinary skill in the art would understand the references.

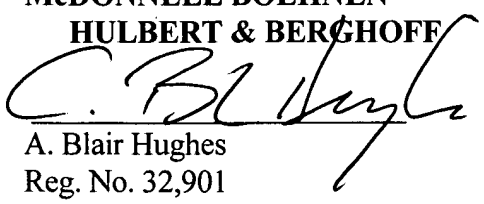
CONCLUSION

The McCormick, Copeland and Stokes references disclose apparatuses and methods for using staining solutions that do not require the addition of further ingredients or mixing in order to be useful. The prior art does not disclose or suggest the applicants invention – that stable ingredients that form unstable staining solution can be individually applied to a biological sample and then mixed while in contact with the biological sample to form a useful staining solution. For this reason, and for the reasons give above and in the Appeal Brief, the examiner's obviousness rejection of claims 1-2 and 4-13 cannot be sustained by the Board.

Respectfully submitted,

McDONNELL BOEHNEN HULBERT & BERGHOFF

Dated: September 22, 2005

By: 

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